

# **AUDITOR'S REPORT**

## **HARRIS HEALTH SYSTEM OPERATING ROOMS ORTHOPEDIC IMPLANTS AND OTHER SPECIAL PATIENT DEVICE CONTROLS**



**April 28, 2016**

**Barbara J. Schott, C.P.A.  
Harris County Auditor**

**Mike Post, C.P.A.**  
*Chief Assistant County Auditor*  
*Accounting Division*

**Mark Ledman, C.P.A., M.P.A.**  
*Chief Assistant County Auditor*  
*Audit Division*



1001 Preston, Suite 800  
Houston, Texas 77002-1817  
(713) 755-6505

FAX (713) 755-8932  
Help Line (713) 755-HELP

**BARBARA J. SCHOTT, C.P.A.**  
**HARRIS COUNTY AUDITOR**

April 28, 2016

Mr. George Masi  
President and Chief Executive Officer  
Harris Health System  
2525 Holly Hall  
Houston, Texas 77054

RE: Harris Health System Operating Rooms Orthopedic Implants and Other Special Patient Device Controls engagement for the three months ended September 30, 2015

The Audit Services Department performed procedures relative to the Harris Health System (Harris Health) Operating Rooms Orthopedic Implants and Other Special Patient Device Controls for the three months ended September 30, 2015. The engagement was performed at the request of Harris Health Management to evaluate critical controls for orthopedic implants and other special patient devices used for patient care in the operating rooms. Procedures were performed to selectively test manual and automated controls for:

- Recording devices used in the operating rooms for patient care.
- Recording tracking information for devices used.
- Recording billable devices used to patient accounts.
- Processing invoices for devices acquired from contract vendors.
- Obtaining approval for devices not acquired from contract vendors.

The engagement process included providing you with a combined engagement and scope letter and conducting conferences with your personnel. The purpose of the letter and conferences were to explain the process, identify areas of concern, describe the procedures to be performed, discuss issues identified during the engagement, and solicit suggestions for resolving the issues. A draft report was provided to you and your personnel for review.

The work performed required our staff to exercise judgment in completing the scope objectives. As the procedures were not a detailed inspection of all transactions, there is a risk that error or fraud was not detected during this engagement. Management therefore, retains the responsibility for the accuracy and completeness of their financial records and ensuring sufficient controls are in place to detect and prevent fraud.

The enclosed Auditor's Report presents the significant issues identified during our procedures, recommendations developed in conjunction with your staff, and any actions you have taken to

Mr. George Masi  
President and Chief Executive Officer

implement the recommendations. Less significant issues and recommendations have been verbally communicated to your staff.

We appreciate the time and attention provided by you and your staff during this engagement.

Sincerely,



Barbara J. Schott  
County Auditor

cc: Harris Health System Board of Managers  
District Judges  
County Judge Ed Emmett  
Commissioners:  
    R. Jack Cagle  
    Jack Morman  
    Steve Radack  
    Gene Locke  
Devon Anderson  
Vince Ryan  
William J. Jackson

## **TABLE OF CONTENTS**

<b>OVERVIEW .....</b>	<b>4</b>
<b>RESULTS .....</b>	<b>6</b>
<b>ISSUES AND RECOMMENDATIONS .....</b>	<b>7</b>
<b>Consignment Device Documentation.....</b>	<b>7</b>
<b>RISK ASSESSMENT AND SUMMARY OF RECOMMENDATIONS.....</b>	<b>9</b>

## OVERVIEW

Gross patient charges for surgical procedures performed in Harris Health Operating Rooms (Operating Rooms) are recorded to patient accounts based on the surgical procedures that are performed, or on the length of time it takes to perform the procedures. Procedure and time charges include amounts to compensate Harris Health for the use of supplies and instruments. However, some orthopedic implants and other special patient devices (collectively called devices in this report) may be charged separately to the patient and/or third party insurance.

The costs of devices that Harris Health purchases for surgical procedures are recorded to the Special Patient Devices account in Harris Health's financial records. Payments recorded to the Special Patient Devices account for Operating Rooms for the three months ended September 30, 2015, are presented below:

Operating Room Location	Amount
Ben Taub General Hospital (Ben Taub)	\$ 1,966,849
Lyndon Baines Johnson General Hospital (LBJ)	1,145,166
Outpatient Center	241,094
<b>TOTAL</b>	<b>\$ 3,353,109</b>

Source: PeopleSoft Financial Records

Management responsible for the Operating Rooms (PeriOperative Management) has developed procedures for managing Operating Rooms supply and device inventory which are designed to ensure safety and high quality care for patients, while cost effectively managing inventory levels. Devices are acquired from vendors that have contractual relationships with Harris Health or with Harris Health's group purchasing organization (GPO).

Some devices are acquired in advance and secured with other supplies in electronic storage cabinets in the Operating Rooms' inventory storage areas. Other devices are held in inventory storage areas as consignment devices. The vendor does not bill Harris Health for consignment devices until they are used for patient care.

There are also devices that are brought to Harris Health for specific procedures by vendor representatives. The vendor representatives arrive with a variety of devices to ensure that the surgeons performing the procedures have the appropriate devices available. Harris Health only pays for the devices that are used for the procedures. The vendor representatives are present in the operating rooms during the procedures and record information for devices that are used.

A Harris Health Circulating Nurse (Circulating Nurse) is assigned and present for each surgical procedure. The Circulating Nurse records information for each procedure into Harris Health's operating room management information system (Epic OpTime), including quantities, descriptions, and tracking information for devices that are used.

The information recorded in Epic OpTime includes information needed to record devices in patient registries, if required. Some devices are required to be recorded in patient registries.

If a vendor representative was present during a procedure, they give the assigned Circulating Nurse a copy of a form or invoice documenting any devices the vendor provided that were used for the procedure. The Circulating Nurse reviews the form or invoice and, if it is correct, signs it and gives it to an Operating Room Materials Coordinator (Materials Coordinator).

The Material Coordinator prepares an electronic purchase requisition for the devices documented on the form or invoice. The requisition is prepared using the GHX eProcurement module (GHX) that is accessed through the materials management system (PeopleSoft). Harris Health contract prices with vendors are loaded in GHX.

If the prices on the form or invoice provided by the vendor agree with the contract prices loaded in GHX, the requisition is electronically forwarded to PeriOperative Management for approval, and then to Harris County Purchasing to generate a purchase order which allows the vendor to be paid. If the prices do not agree, the requisition cannot be processed until the difference is investigated and corrected.

On the first business day following a procedure, the documentation recorded in Epic OpTime by the Circulating Nurse is reviewed by a Clinical Charger and Coding Specialists (Clinical Chargers) in the PeriOperative Services Department. Documentation is reviewed for accuracy and completeness for the procedures performed, operating room time utilized, and any chargeable devices used. Device prices entered in Epic OpTime are also compared to GHX by the Clinical Chargers to ensure that they are correctly entered.

## RESULTS

Based on procedures performed, the critical controls implemented by PeriOperative Management for devices used for patient care in the operating rooms are adequate to ensure that:

- Devices used in the operating rooms are recorded.
- Information recorded for devices used includes tracking information.
- Billable devices used are recorded to patient accounts.
- Devices used without special approval are acquired from contract vendors.
- Data analysis or sampling procedures applied during the audit period did not identify devices supplied by a vendor without a contractual relationship with Harris Health.

Although processes implemented by PeriOperative Management achieved the above objectives for the devices tested, controls could be improved by having vendors provide information on invoices for consignment devices to help identify the patient account.

This issue is discussed in greater detail in the attached Issues and Recommendations matrix.

## ISSUES AND RECOMMENDATIONS

Subject	Background	Issue	Recommendation	Management Response
<p>Consignment Device Documentation</p>	<p>Some vendor consignment devices are kept in the Operating Rooms' inventory storage areas in case they are needed for patient care.</p> <p>Vendor representatives periodically check the inventory levels in the storage areas and replace any devices that were removed for use. At that time, they prepare and send an invoice to Harris Health for the devices used.</p>	<p>One vendor sent invoices to Harris Health for consignment devices that did not include information linking the devices to a patient's account. As a result, invoices could not be traced back to the patients' accounts for 3 of 31 (9.7%) devices tested.</p> <p>The 3 consignment devices were all invoiced to Ben Taub. In addition, the devices were not required to be recorded in a patient registry.</p> <p>Not providing information on invoices to identify the patient's account (while maintaining appropriate patient confidentiality) increases the risk that the devices will not be recorded to the correct account, possibly causing lost revenue, or resulting in</p>	<p>Ben Taub PeriOperative Services Management should instruct the vendor to include information on their invoices to identify the patient accounts. However, the information included should not result in risking unnecessary disclosure of patient information to employees that do not need to know the information (such as clerical employees that process invoices in the Accounts Payable Department).</p>	<p>Synthes is now compliant as the other vendors in ensuring they list individual patient names for charge and reconciliation purposes. Synthes complied with our request the same day the auditor identified they were an outlier in our process.</p>

## ISSUES AND RECOMMENDATIONS

<b>Subject</b>	<b>Background</b>	<b>Issue</b>	<b>Recommendation</b>	<b>Management Response</b>
(Continued) Consignment Device Documentation		the inability to identify patients if there are safety issues or recalls.		

## RISK ASSESSMENT AND SUMMARY OF RECOMMENDATIONS

The risk matrix below presents the assessed level of risk or exposure identified during our procedures. Inherent risk relates to factors that because of their nature cannot be controlled or mitigated by management. Inherent risk includes factors such as legislative changes, number and dollar amount of transactions processed and/or complex nature of transactions. Control risks relate to factors that can be influenced or controlled by management. Controls such as policies and procedures, electronic or manual approvals, system security access, and separation of job responsibilities may be instituted by management in order to mitigate control risk. Control risk is assessed during the planning phase in order to establish the nature, timing, and extent of testing and at the conclusion of the engagement in order to incorporate actions taken to implement our recommendations. The overall risk considers a combination of inherent and control risks.

<b>Inherent Risk:</b>	<b>Control Risk:</b>		<b>Overall Risk:</b>
<input checked="" type="checkbox"/> High <input type="checkbox"/> Moderate <input type="checkbox"/> Low	<b>Prior to Procedures</b>	<b>After Procedures</b>	<input type="checkbox"/> High <input checked="" type="checkbox"/> Moderate <input type="checkbox"/> Low
	<b>Adequate</b>	<b>Adequate</b>	
<b>Type of Procedures:</b> Audit			
<b>Purpose:</b> To evaluate critical controls for orthopedic implants and other special patient devices used for patient care in the operating rooms.			
<b>Outstanding Audit Recommendations:</b>			
<b>Priority Rating:</b>	<b>Audit Recommendations:</b> Harris Health System		
1	Instruct the vendor to include information on their invoice to identify the patient account for the device charge. However, the information included should not result in unnecessary disclosure of patient information to employees that do not need to know the information (such as clerical employees that process invoices).		
<b>Priority Rating</b>	<ol style="list-style-type: none"> <li><b>1. Implement immediately (30 – 90 days)</b> – Serious internal control deficiencies; or recommendations to reduce costs, maximize revenues, or improve internal controls that can be easily implemented.</li> <li><b>2. Work towards implementing (6 – 18 months)</b> – Less serious internal control deficiencies, or recommendations that can not be implemented immediately because of constraints imposed on the department (i.e., budgetary, technological constraints, etc.).</li> <li><b>3. Implement in the future (two – three years)</b> – Recommendations that should be implemented, but that can not be implemented until significant and/or uncontrolled events occur (i.e., legislative changes, buy and install major systems, requires third party cooperation, etc.).</li> </ol>		